

CLAIMS

1. A metered unit dose of a therapeutic composition comprising budesonide in a
5 therapeutically effective amount that is less than about 40 μ g, said composition being
suitable for nasal administration to a mammal in a single dose.
2. A unit dose according to claim 1, comprising from about 16 to about 40 μ g of
budesonide.
- 10 3. A unit dose according to claim 1, comprising about 32 μ g budesonide.
4. A unit dose of a therapeutic composition comprising a therapeutically effective amount of
budesonide that is less than about 40 μ g, wherein the budesonide is in the form of finely
15 divided particles and is suspended in an aqueous medium, said composition being suitable
for administration to a mammal in a single dose.
5. A unit dose according to claim 4, wherein the amount of budesonide is from about 16 to
about 40 μ g.
- 20 6. A unit dose according to claim 4, wherein the amount of budesonide is about 32 μ g.
7. The unit dose of claim 4, further comprising one or more pharmaceutically acceptable
additives selected from the group consisting of thickening agents, isotonicity agents,
25 surfactants, chelating agents, and preservatives.
8. The unit dose of claim 4, wherein the mass equivalent sphere diameter of the budesonide
particles is 10 μ m or less.

9. A formulation comprising a suspension of about 0.6 to about 0.7 mg/ml of finely divided budesonide in water.

10. A formulation according to claim 9, further comprising a pharmaceutically acceptable additive selected from the group consisting of thickening agents, isotonicity agents, surfactants, chelating agents, and preservatives.

11. A formulation according to claim 9, wherein the mass equivalent sphere diameter of the budesonide is 10 μm or less.

12. A formulation according to claim 10, wherein the mass equivalent sphere diameter of the budesonide is 10 μm or less.

13. A therapeutic method of treating or preventing conditions of the upper respiratory tract, the method comprising administering into a nostril of a mammal a metered unit dose of budesonide, wherein said metered unit dose comprises budesonide in a therapeutically effective amount that is less than about 40 μg .

14. A method according to claim 13, in which the condition to be treated is selected from the group consisting of seasonal allergic rhinitis, perennial allergic rhinitis, perennial non-allergic rhinitis, chronic sinusitis, recurrent sinusitis and nasal polyps.

15. A therapeutic method according to claim 13, wherein the unit dose of budesonide is from about 16 μg to about 40 μg .

16. A therapeutic method according to claim 13, wherein the unit dose of budesonide is about 32 μg .

17. A therapeutic method according to claim 13, wherein the condition to be treated is seasonal allergic rhinitis.

18. A therapeutic method according to claim 13, wherein the condition to be treated is perennial allergic rhinitis.

5 19. A therapeutic method according to claim 13, wherein the condition to be treated is perennial non-allergic rhinitis.

20. A therapeutic method according to claim 13, wherein the condition to be treated is chronic sinusitis.

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21. A therapeutic method according to claim 13, wherein the condition to be treated is recurrent sinusitis.

15 22. A therapeutic method according to claim 13, wherein the condition to be treated is nasal polyps.

23. A therapeutic method of treating conditions of the upper respiratory tract, the method comprising metering into the nose of a mammal a therapeutically effective amount of budesonide that is less than about 320 μg per day, delivered as 8 or more unit doses,
20 wherein each unit dose comprises budesonide in an metered amount that is less than about 40 μg .

24. A therapeutic method according to claim 23, wherein the amount of budesonide is about 256 μg per day.

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25. A container containing budesonide and adapted to deliver a unit dose according to claim 1.

26. A container adapted to administer unit doses of a formulation according to claim 9.